

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

Claim 1 (withdrawn) A recombinant expression vector comprising a first nucleic acid having the sequence AGGAGGGTTTTTCAT operatively linked to a second nucleic acid comprising three domains, wherein said first domain has a nucleotide sequence which encodes amino acids 1-225 of an HIV p24 antigen, said second domain has a nucleotide sequence which encodes an HIV gp41 antigen or an antigenic fragment of said HIV gp41 antigen and said third domain has a nucleotide sequence which encodes amino acids 224 to 232 of an HIV p24 antigen.

Claim 2 (withdrawn) The vector of Claim 1, wherein said vector is pGEX7 comprising said first nucleic and second nucleic acids.

Claim 3 (withdrawn) The vector of Claim 1, wherein said first, second and third domains together encode amino acids 1-258 of SEQ ID NO:2.

Claim 4 (withdrawn) The vector of Claim 3, wherein said vector is pGEXp24gp41-ANT.

Claim 5 (withdrawn) The vector of Claim 1, wherein said first, second and third domains together encode amino acids 1-258 of SEQ ID NO:4.

Claim 6 (withdrawn) The vector of Claim 5, wherein said vector is pGEXp24gp41-MVP.

Claim 7 (withdrawn) The vector of Claim 1, wherein said first, second and third domains together encode amino acids 1-258 of SEQ ID NO:6.

Claim 8 (withdrawn) The vector of Claim 7, wherein said vector is pGEXp24gp41-X84328.

Claim 9 (withdrawn) A procaryotic host cell comprising an expression vector of any one of Claims 3,5 or 7.

Claim 10 (withdrawn) A method of producing an HIV p24-gp41 antigen, which comprises

- (a) treating a host cell comprising an expression vector of any one of Claims 3, 5 or 7 under conditions and for a time effective to express said antigen; and
- (b) recovering said antigen.

Claim 11 (withdrawn) A recombinant HIV p24-gp41 antigen produced by the method of Claim 10.

Claim 12 (withdrawn) A composition comprising the recombinant HIV p24-gp41 antigen of Claim 11, wherein said composition is essentially free of procaryotic antigens and other HCV-related proteins.

Claim 13 (withdrawn) A diagnostic system, in kit form, comprising, in an amount sufficient to perform at least one assay, the composition of an HIV p24-gp41 antigen according to Claim 12.

Claim 14 (withdrawn) The diagnostic system according to Claim 13, wherein said HIV p24-gp41 antigen is affixed to a solid matrix.

Claim 15 (withdrawn) A method of assaying a body fluid sample for the presence of antibodies against an HIV p24-gp41 antigen which comprises:

- a) forming an immunoreaction admixture by admixing said body fluid sample with a composition of Claim 12;
- b) maintaining said immunoreaction admixture for a time period sufficient for any of said antibodies present to immunoreact with said antigen to form an immunoreaction product; and
- c) detecting the presence of any of said immunoreaction product formed and

thereby the presence of said antibodies.

Claim 16 (withdrawn) The method of Claim 15, wherein said detecting in step (c) comprises the steps of:

- (i) admixing said immunoreaction product formed in step (c) with a labeled specific binding agent to form a labeling admixture, said labeled specific binding agent comprising a specific binding agent and a label;
- (ii) maintaining said labeling admixture for a time period sufficient for any of said immunoreaction product present to bind with said labeled specific binding agent to form a labeled product; and
- (iii) detecting the presence of any of said labeled product formed, and thereby the presence of said immunoreaction product.

Claim 17 (withdrawn) The method of Claim 16, wherein said specific binding agent is Protein A or at least one of the antibodies anti-human IgG and anti-human IgM.

Claim 18 (withdrawn) The method of Claim 16, wherein said label is a lanthanide chelate, biotin, an enzyme or radioactive isotope.

Claim 19 (canceled) A recombinant expression vector comprising a first nucleic acid having the sequence AGGAGGGTTTTTCAT operatively linked to a second nucleic acid consisting of a nucleotide sequence which encodes amino acids 1-120 of an HCV

capsid antigen.

Claim 20 (canceled) The vector of Claim 19, wherein said vector is pGEX7 comprising said first nucleic and second nucleic acids.

Claim 21 (canceled) The vector of Claim 19, wherein said amino acids are amino acids 1-120 of SEQ ID NO:8.

Claim 22 (canceled) The vector of Claim 21, wherein said vector is pGEX-C120H-V68.

Claim 23 (canceled) The vector of Claim 19, wherein said amino acids are amino acids 1-120 of SEQ ID NO:10.

Claim 24 (canceled) The vector of Claim 23, wherein said vector is pGEX-C120H.

Claim 25 (canceled) The vector of Claim 19, wherein said amino acids are amino acids 1-120 of SEQ ID NO:12.

Claim 26 (canceled) The vector of Claim 25, wherein said vector is pGEX-C120H-ISO2.

Claim 27 (canceled) The vector of Claim 19, wherein said amino acids are amino acids 1-120 of SEQ ID NO:14.

Claim 28 (canceled) The vector of Claim 27, wherein said vector is pGEX-C120H-ISO3.

Claim 29 (canceled) A procaryotic host cell comprising an expression vector of any one of Claims 19, 21, 23, 25 or 27.

Claim 30 (canceled) A method of producing an HCV capsid antigen consisting of amino acid residues 1-120 which comprises

- (a) treating a host cell comprising an expression vector of any one of Claims 19, 21, 23, 25 or 27 under conditions and for a time effective to express said antigen; and
- (b) recovering said antigen.

Claim 31 (canceled) A recombinant HCV capsid antigen produced by the method of Claim 30.

Claim 32 (canceled) A composition comprising a recombinant HCV capsid antigen of Claim 31, wherein said composition is essentially free of procaryotic antigens and other HCV-related proteins.

Claim 33 (withdrawn) A diagnostic system, in kit form, comprising, in an amount sufficient to perform at least one assay, the composition of an HCV capsid antigen according to Claim 32.

Claim 34 (withdrawn) The diagnostic system according to Claim 33, wherein said HCV structural protein is affixed to a solid matrix.

Claim 35 (withdrawn) A method of assaying a body fluid sample for the presence of antibodies against an HCV capsid antigen which comprises:

- a) forming an immunoreaction admixture by admixing said body fluid sample with a composition of Claim 32;
- b) maintaining said immunoreaction admixture for a time period sufficient for any of said antibodies present to immunoreact with said HCV capsid antigen to form an immunoreaction product; and
- c) detecting the presence of any of said immunoreaction product formed and thereby the presence of said antibodies.

Claim 36 (withdrawn) The method of Claim 35, wherein said detecting in step (c) comprises the steps of:

- (i) admixing said immunoreaction product formed in step (c) with a labeled specific binding agent to form a labeling admixture, said labeled specific binding agent comprising a specific binding agent and a label;

- (ii) maintaining said labeling admixture for a time period sufficient for any of said immunoreaction product present to bind with said labeled specific binding agent to form a labeled product; and
- (iii) detecting the presence of any of said labeled product formed, and thereby the presence of said immunoreaction product.

Claim 37 (withdrawn) The method of Claim 36, wherein said specific binding agent is Protein A or at least one of the antibodies anti-human IgG and anti-human IgM.

Claim 38 (withdrawn) The method of Claim 36, wherein said label is a lanthanide chelate, biotin, an enzyme or a radioactive isotope.

Claim 39 (withdrawn) A recombinant expression vector comprising a first nucleic acid having the sequence AGGAGGGTTTTTCAT operatively linked to a second nucleic acid consisting of a nucleotide sequence which encodes an HCV nonstructural 794 antigen having the amino acid sequence of SEQ ID NO:16 or the corresponding sequence from another HCV strain.

Claim 40 (withdrawn) The vector of Claim 39, wherein said expression vector is pGEX7 comprising said first nucleic and second nucleic acids.



Claim 41 (withdrawn) The vector of Claim 40, wherein said vector is pGEX-NS3-794.

Claim 42 (withdrawn) A procaryotic host cell comprising an expression vector of Claim 39.

Claim 43 (withdrawn) A method of producing an HCV nonstructural 794 antigen which comprises

- (a) treating a host cell comprising an expression vector of Claim 39 under conditions and for a time effective to express said antigen; and
- (b) recovering said antigen.

Claim 44 (withdrawn) A recombinant HCV nonstructural 794 antigen produced by the method of Claim 43.

Claim 45 (withdrawn) A composition comprising a recombinant HCV nonstructural 794 antigen of Claim 44, wherein said composition is essentially free of procaryotic antigens and other HCV-related proteins.

Claim 46 (withdrawn) A diagnostic system, in kit form, comprising, in an amount sufficient to perform at least one assay, the composition of an HCV nonstructural 794 antigen according to Claim 45.

Claim 47 (withdrawn) The diagnostic system according to Claim 46, wherein said HCV nonstructural 794 antigen is affixed to a solid matrix.

Claim 48 (withdrawn) A method of assaying a body fluid sample for the presence of antibodies against an HCV nonstructural 794 antigen which comprises:

- a) forming an immunoreaction admixture by admixing said body fluid sample with a composition of Claim 45;
- b) maintaining said immunoreaction admixture for a time period sufficient for any of said antibodies present to immunoreact with said HCV nonstructural 794 antigen to form an immunoreaction product; and
- c) detecting the presence of any of said immunoreaction product formed and thereby the presence of said antibodies.

Claim 49 (withdrawn) The method of Claim 48, wherein said detecting in step (c) comprises the steps of:

- (i) admixing said immunoreaction product formed in step (c) with a labeled specific binding agent to form a labeling admixture, said labeled specific binding agent comprising a specific binding agent and a label;
- (ii) maintaining said labeling admixture for a time period sufficient for any of said immunoreaction product present to bind with said labeled specific binding agent to form a labeled product; and
- (iii) detecting the presence of any of said labeled product formed, and thereby

the presence of said immunoreaction product.

Claim 50 (withdrawn) The method of Claim 49, wherein said specific binding agent is Protein A or at least one of the antibodies anti-human IgG and anti-human IgM.

Claim 51 (withdrawn) The method of Claim 49, wherein said label is a lanthanide chelate, biotin, an enzyme, or a radioactive isotope.

Claim 52 (withdrawn) A recombinant expression vector comprising a first nucleic acid having the sequence AGGAGGGTTTTTCAT operatively linked to a second nucleic acid consisting of a nucleotide sequence which encodes a CAP-B antigen having the amino acid sequence of SEQ ID NO:18 or the corresponding sequence from another HCV strain.

Claim 53 (withdrawn) The vector of Claim 52, wherein said expression vector is pGEX7 comprising said first nucleic and second nucleic acids.

Claim 54 (withdrawn) The vector of Claim 53, wherein said vector is pGEX-CAP-B.

Claim 55 (withdrawn) A procaryotic host cell comprising an expression vector of Claim 52.

Claim 56 (withdrawn) A method of producing an HCV CAP-B antigen which comprises

- (a) treating a host cell comprising an expression vector of Claim 52 under conditions and for a time effective to express said antigen; and
- (b) recovering said antigen.

Claim 57 (withdrawn) A recombinant HCV CAP-B antigen produced by the method of Claim 56.

Claim 58 (withdrawn) A composition comprising a recombinant HCV CAP-B antigen of Claim 57, wherein said composition is essentially free of procaryotic antigens and other HCV-related proteins.

Claim 59 (withdrawn) A diagnostic system, in kit form, comprising, in an amount sufficient to perform at least one assay, the composition of an HCV CAP-B antigen according to Claim 58.

Claim 60 (withdrawn) The diagnostic system according to Claim 59, wherein said HCV CAP-B antigen is affixed to a solid matrix.

Claim 61 (withdrawn) A method of assaying a body fluid sample for the presence of antibodies against an HCV CAP-B antigen which comprises:

- a) forming an immunoreaction admixture by admixing said body fluid sample with a composition of Claim 58;
- b) maintaining said immunoreaction admixture for a time period sufficient for any of said antibodies present to immunoreact with said HCV CAP-B antigen to form an immunoreaction product; and
- c) detecting the presence of any of said immunoreaction product formed and thereby the presence of said antibodies.

Claim 62 (withdrawn) The method of Claim 61, wherein said detecting in step (c) comprises the steps of:

- (i) admixing said immunoreaction product formed in step (c) with a labeled specific binding agent to form a labeling admixture, said labeled specific binding agent comprising a specific binding agent and a label;
- (ii) maintaining said labeling admixture for a time period sufficient for any of said immunoreaction product present to bind with said labeled specific binding agent to form a labeled product; and
- (iii) detecting the presence of any of said labeled product formed, and thereby the presence of said immunoreaction product.

Claim 63 (withdrawn) The method of Claim 62, wherein said specific binding agent is Protein A, or at least one of the antibodies anti-human IgG and anti-human IgM.

Claim 64 (withdrawn) The method of Claim 62, wherein said label is a lanthanide chelate, a biotin, an enzyme, or a radioactive isotope.

Claim 65 (withdrawn) A composition comprising a recombinant HCV capsid antigen consisting of amino acids 1-120 and a recombinant HCV nonstructural 794 antigen consisting of amino acids of SEQ ID NO:16 or the corresponding sequence from another HCV strain, wherein said composition is essentially free of procaryotic antigens and other HCV-related proteins.

Claim 66 (withdrawn) The composition of Claim 65 wherein said recombinant HCV capsid antigen consists of amino acids 1-120 of SEQ ID NO:8.

Claim 67 (withdrawn) The composition of Claim 65 wherein said recombinant HCV nonstructural 794 antigen consists of amino acids of SEQ ID NO:16.

Claim 68 (withdrawn) The composition of Claim 66 wherein said recombinant HCV nonstructural 794 antigen consists of amino acids of SEQ ID NO:16.

Claim 69 (withdrawn) The composition of Claim 65, wherein the ratio by weight of said capsid antigen to said nonstructural antigen is in a range of about 8:1 to about 1:1.

Claim 70 (withdrawn) The composition of Claim 68, wherein the ratio by weight of said capsid antigen to said nonstructural antigen is in a range of about 8:1 to about 1:1.

Claim 71 (withdrawn) A diagnostic system, in kit form, comprising, in an amount sufficient to perform at least one assay, the composition of any one of Claims 65, 68, 69 or 70.

Claim 72 (withdrawn) The diagnostic system according to Claim 71, wherein said HCV capsid antigen and said HCV nonstructural 794 antigen are affixed to a solid matrix.

Claim 73 (withdrawn) A method of assaying a body fluid sample for the presence of antibodies against an HCV capsid antigen or an HCV nonstructural antigen, which method comprises:

- a) forming an immunoreaction admixture by admixing said body fluid sample with a composition of any one of Claims 65, 68, 69 or 70;
- b) maintaining said immunoreaction admixture for a time period sufficient for any of said antibodies present to immunoreact with one or more of said antigens to form an immunoreaction product; and
- c) detecting the presence of any of said immunoreaction product formed and thereby the presence of said antibodies.

Claim 74 (withdrawn) The method of Claim 73, wherein said detecting in step (c) comprises the steps of:

- (i) admixing said immunoreaction product formed in step (c) with a labeled specific binding agent to form a labeling admixture, said labeled specific binding agent comprising a specific binding agent and a label;
- (ii) maintaining said labeling admixture for a time period sufficient for any of said immunoreaction product present to bind with said labeled specific binding agent to form a labeled product; and
- (iii) detecting the presence of any of said labeled product formed, and thereby the presence of said immunoreaction product.

Claim 75 (withdrawn) The method of Claim 74, wherein said specific binding agent is Protein at least one of the antibodies anti-human IgG and anti-human IgM.

Claim 76 (withdrawn) The method of Claim 74, wherein said label is a lanthanide chelate, biotin, an enzyme, a radioactive isotope.

Claim 77 (not entered) A recombinant DNA molecule comprising a vector having a procaryotic promoter operatively linked to a DNA segment, said DNA segment composed of a first nucleotide base sequence operatively linked in frame at its 3' terminus to the 5' terminus of a second nucleotide base sequence, said first sequence having a nucleotide base sequence represented by the formula:



AGGAGGGTTTTTCAT,

corresponding to nucleotides 1-15 of SEQ ID NO.: 1, and said second sequence consists of a nucleotide sequence encoding amino acids 1-120 of the HCV capsid antigen.

Claim 78 (not entered) The vector of claim 77, wherein said vector is pGEX7 comprising said first nucleic and second nucleic acids.

Claim 79 (not entered) The vector of claim 77, wherein said amino acids are amino acids 1-120 of SEQ ID NO:8.

Claim 80 (not entered) The vector of claim 79, wherein said vector is pGEX-C120H-V68.

Claim 81 (not entered) The vector of claim 77, wherein said amino acids are amino acids 1-120 of SEQ ID NO:10.

Claim 82 (not entered) The vector of claim 81, wherein said vector is said vector is pGEX-C120H.

Claim 83 (not entered) The vector of claim 77, wherein said amino acids are amino acids 1-120 of SEQ ID NO:12.

Claim 84 (not entered) The vector of claim 83, wherein said vector is pGEX-C120H-ISO2.

Claim 85 (not entered) The vector of claim 77, wherein said amino acids are amino acids 1-120 of SEQ ID NO:14.

Claim 86 (not entered) The vector of claim 85, wherein said vector is pGEX-C120H-ISO3.

Claim 87 (not entered) A procaryotic host cell comprising an expression vector of any one of claims 77, 79, 81, 83 or 85.

Claim 88 (not entered) A method of producing an HCV capsid antigen consisting of amino acid residues 1-120 which comprises:

- (a) treating a host cell comprising an expression vector of any one of claims 77, 79, 81, 83 and 85 under conditions and for a time effective to express said antigen; and
- (b) recovering said antigen from the fermentation broth following expression by using standard biochemical isolation techniques involving (i) harvest of the bacterial culture (ii) disruption of isolated cell paste (iii) differential extraction and centrifugation of disrupted cells (iv) gel sizing and cationic exchange chromatography steps to separate the HCV capsid antigen from

contaminating materials and (v) collecting the purified HCV antigen for its designated use.

Claim 89 (not entered) A recombinant HCV capsid antigen produced by the method of claim 88.

Claim 90 (not entered) A composition comprising a recombinant HCV capsid antigen of claim 89, wherein said composition is essentially free of procaryotic antigens and other HCV-related proteins.

Claim 91 (currently amended) A diagnostic system, in kit form, comprising, in an amount sufficient to perform ~~at least one~~ an assay, the composition of ~~an a~~ a recombinant HCV capsid antigen according to Claim 32 wherein said composition is essentially free of procaryotic antigens and other HCV-related proteins.

Claim 92 (currently amended) A method of assaying a body fluid sample for the presence of antibodies against an HCV capsid antigen which comprises:

- a) forming an immunoreaction admixture by admixing said body fluid sample with a composition of Claim ~~32~~ 91;
- b) maintaining said immunoreaction admixture for a time period sufficient for any of said antibodies present to immunoreact with said HCV capsid antigen to form an immunoreaction product; and

c) detecting the presence of any of said immunoreaction product formed and thereby the presence of said antibodies.

Claim 93 (currently amended) The method of Claim 36 92, wherein said specific binding agent is Protein A or at least one of the antibodies anti-human IgG and anti-human IgM.

Claim 94 (currently amended) The method of Claim 36 92, wherein said label is lanthanide chelate, biotin, an enzyme, a radioactive isotope or a fluorescent moiety.

Claim 95 (withdrawn) A recombinant expression vector comprising a first nucleic acid having the sequence AGGAGGGTTTTTCAT operatively linked to a second nucleic acid consisting of a nucleotide sequence which encodes an HCV nonstructural 794 antigen having the amino acid sequence of SEQ ID NO:16 or the corresponding sequence from a different HCV strain.

Claim 96 (currently amended) The vector of claim 39 95, wherein said expression vector is pGEX7 comprising said first nucleic and second nucleic acids.

Claim 97 (currently amended) The vector of claim 40 96, wherein said vector is pGEX-NS3-794.

Claim 98 (currently amended) A procaryotic host cell comprising an expression vector of Claim ~~39~~ 95.

Claim 99 (currently amended) A method of producing an HCV nonstructural 794 antigen which comprises

- (a) treating a host cell comprising an expression vector of Claim ~~39~~ 95 under conditions and for a time effective to express said antigen; and
- (b) recovering said antigen.

Claim 100 (currently amended) A recombinant HCV nonstructural 794 antigen produced by the method of Claim ~~43~~ 99.

Claim 101 (currently amended) A composition comprising a recombinant HCV nonstructural 794 antigen of Claim ~~44~~ 100, wherein said composition is essentially free of procaryotic antigens and other HCV-related proteins.

Claim 102 (currently amended) A diagnostic system, in kit form, comprising, in an amount sufficient to perform an assay, the composition of an HCV nonstructural 794 antigen according to Claim ~~45~~ 101.

Claim 103 (currently amended) A method of assaying a body fluid sample for the presence of antibodies against an HCV nonstructural 794 antigen which comprises:

- a) forming an immunoreaction admixture by admixing said body fluid sample with a composition of Claim ~~45~~ 101;
- b) maintaining said immunoreaction admixture for a time period sufficient for any of said antibodies present to immunoreact with said HCV nonstructural 794 antigen to form an immunoreaction product; and
- c) detecting the presence of any of said immunoreaction product formed and thereby the presence of said antibodies.

Claim 104 (currently amended) The method of Claim ~~49~~ 103, wherein said specific binding agent is Protein A or at least one of the antibodies anti-human IgG and anti-human IgM.

Claim 105 (currently amended) The method of Claim ~~49~~ 103, wherein said label is lanthanide chelate, biotin, an enzyme, a radioactive isotope or a fluorescent moiety.

Claim 106 (currently amended) A composition comprising a recombinant HCV capsid antigen consisting of amino acids 1-120 and a recombinant HCV nonstructural 794 antigen consisting of amino acids of SEQ ID NO:16, or the corresponding sequence from another HCV strain, wherein said composition is essentially free of procaryotic antigens and other HCV-related proteins.

Claim 107 (currently amended) The composition of Claim 65 106 wherein said recombinant HCV capsid antigen consists of amino acids 1-120 of SEQ ID NO:8.

Claim 108 (currently amended) The composition of Claim 65 106 wherein said recombinant HCV nonstructural 794 antigen consists of amino acids of SEQ ID NO:16.

Claim 109 (currently amended) The composition of Claim 66 107 wherein said recombinant HCV nonstructural 794 antigen consists of amino acids of SEQ ID NO:16.

Claim 110 (currently amended) The composition of Claim 65 106, wherein the ratio by weight of said capsid antigen to said nonstructural antigen is in a range of about 8:1 to about 1:1.

Claim 111 (currently amended) The composition of Claim 68 109, wherein the ratio by weight of said capsid antigen to said nonstructural antigen is in a range of about 8:1 to about 1:1.

Claim 112 (currently amended) A diagnostic system, in kit form, comprising, in an amount sufficient to perform an assay, the composition of any one of claims 65, ~~68~~, ~~69 or 70~~ 106, 109, 110 or 111.

Claim 113 (currently amended) A method of assaying a body fluid sample for the presence of antibodies against an HCV capsid antigen or an HCV nonstructural antigen, which method comprises:

- a) forming an immunoreaction admixture by admixing said body fluid sample with a composition of any one of claims ~~65, 68, 69 or 70~~ 106, 109, 110 or 111;
- b) maintaining said immunoreaction admixture for a time period sufficient for any of said antibodies present to immunoreact with one or more of said antigens to form an immunoreaction product; and
- c) detecting the presence of any of said immunoreaction product formed and thereby the presence of said antibodies.

Claim 114 (currently amended) The method of Claim ~~74~~ 113, wherein said specific binding agent is Protein A, or at least one of the antibodies anti-human IgG and anti-human IgM.

Claim 115 (currently amended) The method of Claim ~~74~~ 113, wherein said label is lanthanide chelate, biotin, an enzyme, a radioactive isotope or a fluorescent moiety.